K011784

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Date prepared: 17th July, 2001

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92**
Special 510k Device Modification (K011784):
Envoy Patient Monitor - 12Lead ECG/Resp. Module

Establishment Name, Registration Number and Address

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
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Contact person:	Asher Kassel, Director of Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Asher Kassel, Director of Regulatory Affairs

Product Name
Proprietary: ENVOY
Common: Physiological Patient Monitor
Mennen Medical Part Number: 550-010-000 (full system)
554-000-010 (CPU only)

FDA Classification

Classification Name:	Arrhtymia Detector and Alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	74 DSI

Performance Standards

None promulgated

Voluntary Standards

UL 2601-1, IEC 60601-1 for electrical safety for medical equipment
AAMI/ EC 11 - Diagnostic electrocardiograph devices (1991)
AAMI/ EC 13 - Cardiac monitors, heart-rate meters, alarms (1992)
AAMI/ ES 1 - Safe current limits for electromedical apparatus (1993)
IEC 60601-1:
General Requirement for Safety for Medical Electrical Systems - part 1, (1988);
Amendment 1 – 1991-11
Amendment 2 – 1995-03
IEC 60602-2-27:
Medical electrical equipment, Part 2, (1994)
Requirements for safety of electrocardiograph monitoring equipment.

Predicate Device

MENNEN MEDICAL ENVOY PATIENT MONITOR (K001120).

Device Description: Envoy Patient Monitor

The Envoy is a multiparameter physiological patient monitor, capable of monitoring:

- ECG/Heart Rate
- invasive blood pressure
- non-invasive blood pressure
- respiration
- pulse oximetry
- two temperature channels
- cardiac output
- $eTCO_2$

The ***Envoy*** bedside patient monitor consists of a main processing unit, a mountable color monitor, and a module rack housing the various Mennen Medical plug-in *vital signs* modules. The modules monitor the patient's vital signs. Up to six internal modules can be plugged into a module rack. The Envoy can accommodate two module racks. The vital sign data derived from the modules by the Envoy are presented on the monitor as waveform and numeric displays.

ENVOY vital signs modules acquire vital signs data from the patient, and display their waveforms and alarms indications on the ENVOY display unit. Vital signs and waveform information are displayed simultaneously on the ENVOY Display Unit. Up to 8 traces can be displayed at any one time.

The vital signs modules interface with readily available physiologic transducers through electrically isolated patient input connections. After amplification, the signals are digitized, analyzed and displayed. All processing and alarm determination for ECG, Respiration and Invasive Blood Pressure is made using proprietary algorithms and software based on previously marketed Mennen Medical monitoring devices tested against well known and accepted data bases that present representative examples of waveform artifact to be encountered in real case conditions. The SpO_2, Non-Invasive Blood Pressure and EtCO2 Modules incorporate software and/or hardware technology developed by vendors whose products are marketed in the USA.

Information from each vital sign is presented in a separate portion of the display. Each vital sign is labeled for identification and numeric value. Displayed Vital sign information can include: Primary Vital Sign Name, Waveform, Vital Sign Numeric Value, Alarm Status Message.

Operation of the ENVOY is accomplished by interaction with front panel controls on the main processor unit. A quick-knob control allows direct interaction with displayed menus for direct parameter selection and setup. Where manual entry of alphanumeric information is required, a menu keyboard menu is display.

ENVOY is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such it is not a life supporting, nor life sustaining device; nor is it implantable and therefore sterility is not a consideration.

ENVOY complies with IEC 601-1 Medical Electrical Equipment, IEC 601-2-27 Safety of Electrocardiographic monitoring, IEC 601-2-30 Requirements for Automatic Cycling Indirect Blood Pressure monitoring, AAMI/ANSI SP-10/A1 Electronic or Automated Sphygmomanometers, IEC 601-2-34 Requirements for Invasive Blood Pressure monitoring, AAMI/ANSI ES1 Safe Current Limits for Electromedical Apparatus, and AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms. ENVOY is not a kit, does not contain any drug or biological products and is not for prescription use.

Functional Description of the Envoy 12Lead ECG/Resp. module

The ECG/Resp. module is the source of all ECG data in the ***Envoy*** bedside monitor. ECG is measured using a multi-lead cable via electrodes attached to the patient's chest.

Monitoring the ECG produces a continuous waveform of cardiac electrical activity to enable an accurate assessment of a patient's current physiological condition. With the ECG module, you can use a 3, 5 6 or 10 lead electrode ECG cable set to display up to 12 selectable ECG leads in up to three channels.

The 12 Lead ECG/Resp. module is housed in the ***Envoy*** module rack, where it occupies a single slot. It includes ECG and respiration monitoring.

ENVOY Intended Use:

ENVOY is intended for use as a multiparameter physiological patient monitoring system.

The ENVOY can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the ENVOY to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical ENVOY is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Substantial Equivalency Information:

The following tables summarize and compare data on the Mennen Medical ENVOY 3/5/6 Lead ECG/Resp. module (predicate device - K001120) to the subject of this Special 510(k) submittal, the ENVOY 12 Lead ECG/Resp. module (modified device). We submit that the ENVOY 12 Lead ECG/Resp. module (modified device) is substantially equivalent to the Mennen Medical ENVOY 3/5/6 Lead ECG/Resp. module (predicate device - K001120), available in the U.S. market.

SE Comparison: 12 Lead ECG/Resp. module vs 3/5/6 Lead ECG/Resp. module

The following tables summarize and compare data on the Mennen Medical ENVOY 3/5/6 Lead ECG/Resp. module (predicate device - K001120) to the subject of this Special 510(k) submittal, the ENVOY 12 Lead ECG/Resp. module (modified device).

Monitored Parameters ECG/HEART RATE	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
Part/Option Number	551-104-000	C51-112-000
Monitored Leads	Multi-lead ECG Module (3 /5/6-leads)	Multi-lead ECG Module (3/5/6/12 leads) – No Substantial Difference
Sampling Rate and Resolution	641 Hz sampling rate 22 bit resolution	the same
Frequency Response – analog output	Diagnostic: 0.05 to 150 Hz Monitor: 0.5 to 40 Hz Exercise: 1.0 to 25 Hz According to ANSI/AAMI EC11[10] para.3.2.7.2	the same
Input Impedance	20M ohm: typical 5M ohm: differential, dc to 10Hz 2.5M ohm: differential 10 to 100 Hz as per ANSI/AAMI EC13[9] para.3.2.9.2	the same
Common Mode Rejection (CMR)	120 dB, minimum Lead Fault Detection based on impedance	the same
Baseline Recovery	within 3 sec, 1 sec after lead switch	the same

Monitored Parameters ECG/HEART RATE	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
Dynamic Range	differential voltage of up to ± 5mv at a rate up to ±320 mV/sec as per ANSI/AAMI EC13[9], para. 3.2.9.1	the same
Noise	<30 microVp-p ANSI/AAMI EC13[9] para.3.2.9.3	the same

Monitored Parameters ECG/HEART RATE	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
Gain Levels	250 – 8000	the same
Pacemaker Detection and Rejection	Amplitude: 2 mV to 700 mV Width: 0.1 ms to 2.0 ms as per ANSI/AAMI EC13 [9] para.3.1.4 Pacemaker flag inserted into displayed waveform	the same
Patient Isolation	Meets ANSI/AAMI ESI-1985 standard for Safe Current Limits for Electromedical Apparatus (5kV dc, 2.5kV AC	the same
Heart Rate (HR) Counting	20 to 300 BPM	the same
HR Accuracy	± 2 BPM. Values below 20 are recorded as zero	the same
QRS Detection Range	0.25 to 5.0 millivolt height 70 to 120 milliseconds width	the same
Leads analyzed for:	Heart Rate and Arrhythmia Configuration Top two displayed	the same
HR Alarm Settings	20 (low) to 250 (high), non-overlapping	the same
Lead Fault Sense	when ECG electrode is interrupted or becomes marginal	the same
Defib. Pulse Protection	5KV as per ANSI/AAMI EC13 (9), clause 3.2.2.2 and per IEC 601-2-27 (12), clause 17,101 and 102	the same
Degree of protection against electrical shock	Type CF	the same

Monitored Parameters ECG/HEART RATE	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
Electrosurgical Interference Suppression Provided	Yes	the same

Monitored Parameters RESPIRATION	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
Part/Option Number	551-104-000	C51-112-000
Lead Selection	RA-LA (transthorac) or RA-LL (transabdominal)	the same
Frequency Response	0.13 to 2.5 Hz (-3 dB)	the same
Impedance Range	100 to 3000 ohm @ 100 kHz	100 to 1500 ohm @ 65 kHz - No Substantial Difference
Respiration Sensitivity Range	0.2 ohm to 5.0 ohm	the same
Respiration Rate Counting Range	8 to 150 BPM	8 to 120 BPM - No Substantial Difference
Overload Recovery Time	typically 1 sec, max 10 sec	the same
Lead Fault Sense	>3K ohm	the same
Manual threshold mode	0.2 ohm/1000 ohm (0.02%) to 5 ohm/1000 ohm (0.5%) at 20 BPM	0.2 ohm/1500 ohm (0.013%) to 5 ohm/1000 ohm (0.33%) at 20 BPM
Automatic Threshold	0.35 ohm/1000 ohm (0.035%) to 5 ohm/1000 ohm (0.5%) at 20 BPM	the same
Alarm Settings	Low rate: 0 - 150 BPM High: rate: 8 - 150 BPM	Low rate: 0 - 120 BPM High: rate: 8 - 120 BPM - No Substantial Difference
Apnea Alarm Delay	10 - 90 sec, selectable (default 10 sec.)	10 - 90 sec, selectable (default 10 sec.) - the same
Apnea Alarm Reset	Automatic as defined by System administrator (default 3 breaths)	the same

Displayed Parameters	ENVOY **3/5/6 Lead ECG/Resp. module**	ENVOY **12 Lead ECG/Resp. module**
ECG	Yes	Yes
Heart Rate	Yes	Yes
Respiration	Yes	Yes

Alarm Indications:	**ENVOY 3/5/6 Lead ECG/Resp. module**	**ENVOY 12 Lead ECG/Resp. module**
ECG	Visual & Sound	Visual & Sound
Heart Rate	Visual & Sound	Visual & Sound
Respiration	Visual & Sound	Visual & Sound

Display Functions	**ENVOY 3/5/6 Lead ECG/Resp. module**	**ENVOY 12 Lead ECG/Resp. module**
Change ECG Lead Selection	YES	YES
Display of Arrhythmia Information	YES	YES
Data Review: Trends	YES	YES
Data Review: Tabular	YES	YES
User defined Configuration Setup	YES	YES
User defined Default Settings	YES	YES

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Conclusion of comparison of Technological characteristics:

We consider the 12 Lead ECG/Resp. module to be substantially equivalent to the 3/5/6 Lead ECG/Resp. module and we submit that any differences between the two modules:

*fall within the scope of a Special 510(k) Device Modification
*do not raise any new issues of safety and effectiveness

Testing

The 12 Lead ECG/Resp. module of the ***Envoy*** patient monitor has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies to applicable industry and safety standards. The 12 Lead ECG/Resp. module of the Envoy patient monitor has also been clinically tested and evaluated in a local hospital.

Signature:

A. Kassel

Asher Kassel
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 1 6 2001

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ISRAEL

Re: K011784
Trade Name: Envoy Patient Monitor, 12 Lead ECG/Resp. Module
Regulatory Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: July 17, 2001
Received: July 19, 2001

Dear Mr. Kassel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

ENVOY is intended for use as a multiparameter physiological patient monitoring system.

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Division of Cardiovascular & Respiratory Devices
510(k) Number K011784

Prescription Use ✓